Unverdorben, Martin

From: Cindy Dempsey [Cindy.Dempsey@mdsps.com]
Sent: Wednesday, December 11, 2002 3:52 PM
To: Martin.Unverdorben@pmusa.com
Cc: Kimberly Prchal; Nancy Wang; Linda Cook
Subject: FWD: Clarification for E4 revisions

Sensitivity: Confidential

FWD: Clarification for E4 revi...

Dr. Unverdorben,

I apologize that I was unable to return your e-mail more promptly this morning. I have spoken with Kim and Nancy who have told me a December 31st deadline was discussed at this morning's meeting so that is the deadline I am trying to meet.

I received an e-mail from Robin at Philip Morris showing proper italicization of the biomarkers. I have updated our biomarker document, will update the report, and will disperse this information among the MDS team.

In order to finish the revisions I will still need feedback from you on the remainder of my questions (Questions 1,2, and 4) from the November e-mail. I have attached a copy of the e-mail containing these questions.

Also, in your "recommendations for interpretation of data" you asked us to look at a few biomarker trends where a significant day effect was noted. I reviewed this information with Nancy and Dr. Kisicki. Dr. Kisicki thought that the fluctuations in the biomarkers of harm noted across study days was not clinically significant. While these study day effects may be due to environmental issues of confinement, we were unable to pinpoint a precise study event or events which could explain these trends. To what extent would you like this addressed in the report? Would you like this information mentioned in the discussion. Or, because we were not able to pinpoint a causative event, do you even want further discussion added?

Thank you for your assistance. Best regards, Cindy

Done 4/Jan/03

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